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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,261

02/18/2004

Steven Rubin

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04/15/2008

WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
ONE CENTURY TOWER, P.O. BOX 1832
NEW HAVEN, CT 06508-1832

EXAMINER

ROGERS, JUNE MARIE

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

04/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,261	RUBIN, STEVEN	
	Examiner	Art Unit	
	JUNE ROGERS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52 and 54-75 is/are pending in the application.
- 4a) Of the above claim(s) 59-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52, 54-58 and 63-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/03/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claim 52 and sodium olefin sulfonate as a cleanser, in the reply filed on February 11, 2008 is acknowledged.

Claims 59-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 11, 2008.

Claims 52, 54-58 and 63-75 are under consideration in this Application.

Priority

This application claims priority to US Provisional Application No 60/448,688 filed on February 19, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52, 54-58 and 63-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over OHalloran et al (US Patent No. 6,168,798), Murad (US Patent No. 6,071,541) and Murad (US 2002/0054918).

O'Halloran et al teaches compositions for the treatment of skin conditions such as acne comprising 0.1% to 15% of salicylic acid (claims 1 and 8) and further comprising ingredients such as emollients, antimicrobials, humectants, surfactants, fragrances and colorants (claim 7). O'Halloran et al. exemplifies a non-irritating composition comprising 24% c14-c16 olefin sulfonate (a cleanser); .52% salicylic acid, and cocamidopropyl betaine (viscosity booster) (col. 8, table 2). O'Halloran further teaches the antimicrobial can be farnesol or farnesol acetate (col. 5, line 66).

Murad (6,071,541) teaches compositions for the treatment of acne comprising 1 to 12% of an acidic component (such as salicylic acid); (see claim 4 and 8) and 0.1 to 1.5% weight of an antimicrobial farnesol (claim 24). Murad further teaches the composition can contain 10.1 to 99.1% of at least one surfactant, a stabilizer a preservative, a moisturizer, anti-inflammatory agent, anti-oxidant and a coloring agent (claim 9). Murad et al. further teaches the acne management formula which comprising salicylic acid and glycolic acid (an exfoliant) for the spot treatment of acne (see example 4 and col. 22, lines 10-14).

The prior art does specifically teach sodium hyaluronate, however; Murad (US 2002/0054918) teaches compositions for the prevention, treatment and management of inflammatory skin conditions (such as acne; see [0028]) comprising 0.01% to 20% weight of a hydrophilic moisturizing agent such as hyaluronic acid ([0021-0022]) and further comprising an exfoliate such as salicylic acid (claims 1, 6 and 13) as well as containing 10.1 to 99.1% of at least one surfactant, a stabilizer a preservative, a moisturizer, anti-inflammatory agent, anti-oxidant and a coloring agent (claim 16). The

use of the salt form of an acid is routine practice to one skilled in the art the therefore is obvious.

As to Applicant's language regarding a kit, acne kits are well known in the prior art and are simply steps comprising different composition in the treatment process for acne. For example, Murad (US Patent No. 6,071,541), discloses a four step acne treatment regimen in which subjects were given four compositions (a kit) and directions on the order of application and frequency of use (see col. 21-22).

Accordingly, "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious" KSR v. Teleflex, 127 S. Ct. 1727, 1740 (2007) (quoting Sakraida v. A.G. Pro., 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent is claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issuer of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S. Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is.....a person of ordinary creativity, not an automaton." Id. at 1742.

Consistent with this reasoning, it would have obvious to provide a kit comprising various compositions, each with the function of treating acne, with ingredients within the

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prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

As to the ratios, recited in instant claims 66, 67 and 71-73, the prior art is silent as ; however the prior art discloses broad ranges for each component. Accordingly, "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). >See also *In re Harris*, 409 F.3d 1339, 74 USPQ2d 1951 (Fed. Cir. 2005). Stated differently, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus it would have been obvious to have optimized the components of Applicant's invention to provide a composition with the most beneficial treatment properties.

Conclusion

No claims allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JUNE ROGERS whose telephone number is (571)270-3497. The examiner can normally be reached on M-F 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Juné M. Rogers

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612